SUN BIOTECHNOLOGIES, INC.
A PREFERRED PROVIDER NETWORK

OCT 1 0 2000

K 002104

Section E – 510(k) Summary

510(k) Summary

Submitted By:	MaryRose Cusimano, Ph.D.
Business Address:	7481 W. Oakland Park Blvd. Ste. 305
City, State, Zip:	Ft. Lauderdale, Fl. 33319
Office Phone:	954-578-6884
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Date Prepared: July 4, 2000
Contact Person: MaryRose Cusimano, Ph.D.

Product Trade Name:	Combined Physiological Monitoring System
Common Name:	CPMS, Surface Electromyography, Range of Motion System
Classification Name:	Electromyography Diagnostic (890.1375)

List of Predicate Devices to which we claim substantial equivalence:

1. Integrated Movement Analyzer K944787.
2. Davicon Medac System K914920.
3. Neurocom EMG K901732.
4. Nicolette Viking II K890495

Description of CPMS Device:
The Combined Physiological Monitoring System (CPMS0 combines up to 32 channels, allowing for up to 18 channels of surface EMG to monitor any muscle group in the body. The system also features lead status circuitry to indicate correct placement of all EMG electrodes. The additional channels monitor a functional capacity sensor, a range of motion arm and Jamar grip strength and pinch-strength measurement devices.

Intended Use of CPMS Device:
Surface electromyography with range of motion, functional capacity assessment, grip and pinch strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2000

MaryRose Cusimano, Ph.D.
7481 W. Oakland Park Boulevard, #305
Ft. Lauderdale, Florida 33319

Re: K002104
Trade Name: Combined Physiological Monitoring System
Regulatory Class: II
Product Code: IKN
Dated: July 4, 2000
Received: July 12, 2000

Dear Dr. Cusimano:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002104

Device Name: Combined Physiological Monitoring System.

Indications For Use:

Surface electromyography with range of motion, functional capacity assessment, grip and pinch strength.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002104

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)